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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,519	01/14/2005	Gregor John McLennan Anderson	PG4657USw	5645

23347 7590 12/11/2009
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EXAMINER

KUMAR, RAKESH

ART UNIT	PAPER NUMBER
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3651

NOTIFICATION DATE	DELIVERY MODE
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12/11/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/502,519	Applicant(s) ANDERSON ET AL.	
	Examiner RAKESH KUMAR	Art Unit 3651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) 32-37, 50 and 51 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 79 is/are allowed.
- 6) ☒ Claim(s) 1-31, 38-47 and 52-78 is/are rejected.
- 7) ☒ Claim(s) 16-18, 53 and 54 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/10/2009; 11/12/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

Final Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 rejected under 35 U.S.C. 103(a) as being unpatentable over Everett (EP000469814A1) in view of Widerstrom (US 6,698,425).

Referring to claims 1,2,7,39,40,70 and 78. Everett discloses a medicament dispenser (Figure 1) comprising;

plural elongate form medicament carrier (38), each having multiple distinct medicament dose portions (40) carried thereby,

the medicament dose portions of each carrier containing a medicament active,

said dispenser having a dispensing mechanism (including 27,35,31,33 and 32) which is adapted to operate, upon each actuation of the dispenser to dispense a single distinct medicament dose portion (40) carried by each of said plural medicament carrier (38), said mechanism comprising;

at least one receiving station (34) for receiving each of the plural medicament carriers (Figure 1);

a release (31) for releasing in combination a distinct medicament dose portion (41a) from each of the plural medicament carders (38 and 38a) on receipt thereof by said receiving station (34);

an outlet (22), positioned to be in communication with the combination of distinct medicament dose portions (40) releasable by said release (31) and through which a user is able to access said combination of distinct medicament dose portions; and

at least one indexer (27) for individually indexing the distinct medicament dose portions (40) of each of the plural medicament carriers (38 and 38a).

Everett does not disclose the dispenser comprising plural medicament carriers wherein upon actuation each of the plural carriers dispenses a dose.

Widerstrom discloses a powder inhaler dispenser (Figure 3a) wherein a plural medicament carrier (9b) when actuated (16; Figure 6) releases a distinct dose that can be inhaled through the mouth piece (12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Everett to include a carrier comprising a plurality of carriers wherein the actuation results in dispensing a distinct dose because dose comprising a multiple medicaments can provide better medication option for the user.

Referring to claim 3. Everett discloses a medicament dispenser wherein a common receiving station (34) receives each of the plural medicament carriers (38 and 38a).

Referring to claim 4. Everett discloses a medicament dispenser comprising plural distinct receiving stations (34) each for receiving a single medicament carriers (38 and 38a).

Referring to claim 5. Everett discloses a medicament dispenser wherein said release (31) comprises means to access medicament carried by said medicament carrier (38) by a rupturing, puncturing, tearing or peeling action (see Figure 1).

Referring to claim 8. Everett outlet (22) is shaped to encourage mixing of the medicament.

Referring to claims 9 and 10. Everett discloses plural distinct indexers (see teeth on member 26 engaged member 39; Figure 5).

Referring to claim 11. Everett discloses plural distinct indexers as being mutually coupled (see gear 26).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6,12-15,19-31,38,41-49,52,56-69 and 71-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Everett in view of Widerstrom and further in view of Davies (US 5,873,360).

Referring to claim 6. Everett discloses all claimed limitations of claim 6 however Everett does not disclose a release comprising a peelable blister strip.

Davies discloses a medicament dispenser (Figure 2) wherein the release comprises a peelable blister strip (401).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the teaching of Everett in view of Widerstrom to include a peelable blister strip as a medicament carrier as taught by Davies because the dispenser would be operable with different types.

Referring to claims 12,19,20,30,38,41-49,56-69 and 71-78. See Claim rejections above. Davies discloses a medicament dispenser (Figure 2) for containing plural blister strip (401) form medicament carriers, each having multiple distinct pockets (multiple 402 member on strip 401) for containing medicament dose portions, wherein said pockets (402) are spaced along the length of and defined between two peelable sheets (403a and 404) secured to each other, said dispenser having a dispensing mechanism (482b; Figure 16b) for dispensing the medicament dose portions (402) contained within said plural medicament carriers (401), said mechanism comprising, an opening station (below member 218) for receiving a pocket (402) of each of said medicament carriers (401);

at least one peeler (204; Figure 9) positioned to engage a base sheet and a lid sheet of a pocket (402) which has been received in said opening station for peeling apart such a base sheet and lid sheet, to open such a pocket;

an outlet (220), positioned to be in communication with an opened pocket (402) through which a user can access a medicament dose portion from such an opened pocket; and

at least one indexer (including 224,226,227 and 222) for individually indexing the distinct pockets (402) of each of the plural medicament carriers (401).

Further more, the combinations of dosages and the type of medications contained within the medicament pockets can altered to suit a specific need of a user.

Referring to claim 30. See claim rejections 9-11 above.

Referring to claim 13. Everett discloses a dispenser for containing from two to four blister strips (Figure 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the teaching of Everett to include multiple blister strips in the dispenser because the useable life of the dispenser could extended.

Referring to claims 14 and 15. See rejections above.

Referring to claim 21. Davies discloses a medicament dispenser (Figure 2) wherein said peeler (204) includes a lid driver (214) for pulling apart said lid sheet (404) and the base sheet (403).

Referring to claims 22,25 and 26. Davies discloses a medicament dispenser (Figure 2) wherein the lid driver comprises a wheel (214) on which the lid is wound up, said wheel being arranged to progressively collapse (flexible) as the lid sheet becomes wound (see element 474; Figure 14).

Referring to claim 23. Davies discloses a medicament dispenser (Figure 2) comprising control means (424) to control the movement of the lid driver (474).

Referring to claim 24. Davies discloses a medicament dispenser (Figure 2) wherein the control means comprises a clutch (470).

Referring to claims 27 and 28. Davies discloses a medicament dispenser (Figure 2) wherein the flexible member (474) comprises a variable length spring (variable in the diameter of the flexible member).

Referring to claim 29. Davies comprises a guide (see interior portion of dispenser molded to guide the lid and the base sheet of the medicament carrier) for guiding the lid and the base sheets.

Referring to claim 31. Everett discloses chambers (17; Figure 1) for housing plural medicament carriers prior to opening.

Allowable Subject Matter

Claim 79 allowed.

Claims 16-18,53,54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 1 and 6 have been considered but are moot in view of the new ground(s) of rejection. See modified rejections above including newly cited references of Widerstrom.

Applicant argues "Everett does not disclose a device wherein "the medicament dose portions of each carrier containing a medicament active, or a mixture of medicament actives, which is" different from that in the medicament dose portions of the other carrier(s)." It is in the view of the Office that a carrier strip can be manufactured to carry different types of medicament actives however the overall function of the apparatus as disclosed Everett would not change.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Davies and

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Everett disclose the use of a medicament carries although the carriers may not be the exact same, it is the teaching that is gleaned from one reference to another.

In regards to the claimed limitations “multiple distinct medicament dose portion” as recited in the claims, the reference of Everett discloses the carrier (38) comprising a distinct medicament dose portions in each of the blisters cavities and thus multiple cavities comprise a “multiple distinct medicament dose portion.”

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to RAKESH KUMAR whose telephone number is (571) 272-8314. The examiner can normally be reached on M-F 8 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gene Crawford can be reached on (571) 272-6911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gene Crawford/
Supervisory Patent Examiner, Art
Unit 3651

/RAKESH KUMAR/
Examiner, Art Unit 3651